

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2062724	(X3) Date Survey Completed 02/11/2021
Name of Provider or Supplier Dermatology Associates Of Georgia, Llc	Street Address, City, State 2061 Peachtree Road, Suite 400, Atlanta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 22, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the office manager , the lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the 2019 PT documents reveals the LD failed to attest that PT samples were tested in the same manner as patient specimens for 2019 event #3. 2. Interview with the office manager on February 11, 2021 at 11:06 am in the breakroom confirms the LD did not sign the 2019 Event #3 attestation.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing</p>

samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of the American Academy of Family Physicians (AAFP) proficiency test (PT) records and interview with the office manager, the laboratory failed to maintain a copy of all records. Findings include: 1. Review of the AAFP PT documents, reveals the lab failed to maintain the result page for 2019 event #3. 2. Interview with the office manager on February 11, 2021 at 11:06 am in the breakroom confirms the lack of the PT result page for the 2019 Event #3.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records for Dermatophyte test media (DTM) and staff interview, the facility failed to perform the required quality control on each batch of media used to perform fungus cultures. Findings include: 1. Review of 2019 and 2020 quality control (QC) records reveals the laboratory is not performing in-house QC on DTM media. 2. Interview with the office manager on February 11, 2021 at 10:55 am in the breakroom confirms the laboratory is not performing the media QC as required.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records for Dermatophyte test media (DTM) and staff interview, the facility failed to perform the required sterility check on each batch of media used to perform mycology cultures. Findings include: 1. Review of 2019 and 2020 quality control (QC) records reveals the laboratory is not performing in-house sterility check on DTM culture media. 2. Interview with the office manager on 02/11

/2021 at 10:57 am in the breakroom confirms the lab is not performing the sterility check as required.

D5523

PARASITOLOGY
CFR(s): 493.1264(a)(d)

The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) documents and staff interview, the laboratory failed to perform or document controls on wet mounts as required. Findings include:
1. Review of 2019 and 2020 QC documents revealed no QC records available on wet mounts at the time of the survey. 2. Interview with the office manager on 02/11/2021 at approximately 10:57 a.m. in the breakroom, confirmed QC was not performed on wet mounts.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of proficiency test (PT) records and interview with the office manager, the lab director failed to review the PT results upon return from American Academy of Family Physicians (AAFP). Findings include: 1. Review of the AAFP PT documents, reveals the LD failed to review PT results for 2019 event #3. 2. Interview with the office manager on February 11, 2021 at 11:06 am in the breakroom confirms the lack of PT review for the 2019 Event #3.